test kit or other device that measures the concentration of sanitizing solutions in appropriate units of measurement shall be used as necessary to ensure compliance with this subsection at all times.

ATCP 65.36 Receiving milk and dairy products. (1) MILK FROM DAIRY FARMS. (a) No dairy plant operator may collect or receive milk from a dairy farm located in this state, unless the milk producer holds a current milk producer license for that dairy farm under s. 97.22 (2), Stats., and s. ATCP 65.02.

(b) No dairy plant operator may collect or receive a milk shipment from a dairy farm in this state unless a person, licensed under s. 97.17 or 98.146, Stats., does all the following before that milk shipment is commingled with milk from any other dairy farm:

1. Collects a sample of milk from the shipment, according to s. ATCP 65.38.

2. Accurately measures and records the temperature and quantity of milk in the shipment.

Note: A dairy plant operator shall comply with applicable requirements under subch. V , which requires dairy plant operators to sample and test producer milk and report test results. Dairy plant operators must reject milk shipments and take follow-up action in some cases.

(2) GRADE A MILK FROM DAIRY FARMS. No dairy plant operator may collect or receive as grade A milk any of the following:

(a) Milk from a dairy farm in this state, unless the milk producer holds a current grade A permit for that dairy farm under s. 97.22 (3), Stats., and s. ATCP 65.02 (10).

(b) Milk from a dairy farm in any other state, unless the milk producer holds a current grade A permit for that dairy farm from the responsible regulatory authority in that state.

(3) BULK MILK TANKER DELIVERIES AND SHIPMENTS. (a) No dairy plant operator may receive or ship any grade A milk or grade A fluid milk products transported in a bulk milk tanker, unless the bulk milk tanker operator holds a current grade A permit for that bulk milk tanker issued under s. 97.21 (2) (b), Stats., and s. ATCP 82.02 (7) or issued by another state's regulatory agency.

(b) Before a dairy plant operator unloads milk from a bulk milk tanker or commingles it with milk from another milk producer, the dairy plant operator shall test the bulk shipment for drug residues according to s. ATCP 65.72 (3).

(c) An on-farm dairy plant may not receive milk from the same dairy farm which is transported by means other than a bulk milk tanker unless each bulk shipment of milk is sampled and the milk is tested for drug residues according to s. ATCP 65.72 (3). After the sampling, all remaining unpasteurized milk shall be pasteurized and all equipment that contacted the unpasteurized milk shall be cleaned and sanitized before the next receipt of unpasteurized milk by the dairy plant. The sample of milk shall be obtained from one of the following locations:

1. The dairy farm bulk milk tank or silo.

2. An unpasteurized milk tank, silo, other unpasteurized milk storage container, or vat pasteurizer raw milk receptacle in the dairy plant.

(4) GRADE A DAIRY PLANT MAY NOT RECEIVE GRADE B MILK. A grade A dairy plant operator may not process grade B milk at a grade A dairy plant unless the division authorizes that processing in writing. A grade A dairy plant operator may not receive, transfer, or process grade A milk or dairy products through the same equipment used to receive, transfer, or process grade B milk or dairy products unless the dairy plant operator first rinses the equipment.

(5) MANUFACTURED DAIRY INGREDIENTS; APPROVED SOURCES. Manufactured dairy ingredients used in the manufacture or processing of dairy products shall originate from dairy plants licensed under s. 97.20, Stats., and this chapter, or licensed or inspected under laws of other states or nations deemed acceptable by the FDA.

(6) RECEIVING FACILITIES. (a) A dairy plant's facilities for receiving milk shipments shall be constructed and maintained in compliance with s. ATCP 65.24 and shall be separated from other areas of the dairy plant as required by s. ATCP 65.24 (7).

(b) An on-farm dairy plant may not receive milk from the same dairy farm unless the milk is transported in a bulk milk tanker and received in a facility complying with s. ATCP 65.24 or stored on the dairy farm in a bulk milk tank or silo that is directly connected to an raw milk tank, silo, other raw milk storage container, or vat pasteurizer raw milk receptacle in the dairy plant.

(7) CLEANING AND SANITIZING BULK MILK TANKERS. A dairy plant operator shall ensure that bulk milk tankers transporting milk or dairy products to or from a dairy plant are cleaned and sanitized after each day's use as required by s. ATCP 82.08.

(8) CLEANING AND SANITIZING MILK CANS. If a dairy plant operator receives raw milk in cans, the dairy plant operator shall clean, sanitize, and thoroughly dry those cans before the cans are removed from the dairy plant for reuse. Can washing equipment shall be kept clean and in good repair.

ATCP 65.38 Collecting milk samples. (1) SAMPLE REQUIRED. A dairy plant operator who receives a milk shipment from a milk producer shall collect a representative milk sample from that shipment. Sufficient agitation or a milk sampling method approved by the division shall be used to ensure that the milk sample is representative of the milk shipment. A person licensed under s. 97.17 or 98.146, Stats., shall collect the sample before the dairy plant operator commingles the milk with milk from any other milk producer.

(2) SAMPLE COLLECTED AT THE DAIRY FARM. A bulk milk weigher and sampler who collects a bulk milk shipment from a dairy farm shall collect the milk sample for the dairy plant operator, under sub. (1), in accordance with ch. ATCP 82. The bulk milk weigher and sampler shall

promptly deliver the sample to the dairy plant operator, or to a milk testing laboratory designated by the dairy plant operator.

(3) SAMPLE COLLECTED FROM BULK TRANSPORT CONTAINER. A person who receives a bulk transport container at a dairy plant shall collect the milk sample for the dairy plant operator under sub. (1), in accordance with ch. ATCP 82. The person shall promptly deliver the sample to the dairy plant operator or to a milk testing laboratory designated by the dairy plant operator.

(4) INCREASED SAMPLING FREQUENCY. If milk from any dairy farm violates a standard under s. ATCP 65.70 on any single test, the dairy plant operator shall do any of the following:

(a) Collect and test a milk sample from that farm at least once every 2 days until a subsequent test shows that the violation has been corrected.

(b) Reject milk shipments from the producer, if the operator is required to reject those milk shipments under s. ATCP 82.10 (4), 65.70 (2) (f), or 65.70 (4).

ATCP 65.40 Storing and handling milk and dairy products. (1) GENERAL. Dairy products shall be protected from contamination and decomposition while being received, processed, handled, conveyed, or held at a dairy plant. Dairy products shall be received, processed, handled, conveyed, and held in a manner that keeps the products in a safe, wholesome, and unadulterated condition.

(2) STORAGE TEMPERATURES. (a) Milk and dairy products shall be stored at temperatures listed in pars. (b) to (e), unless the division has authorized alternative temperature limits in writing. An authorization by the division shall be valid for 5 years, and may be renewed upon a written request from the dairy plant operator.

(b) Except as provided under par. (e), unpasteurized grade A milk and grade A dairy products received for processing at a dairy plant shall be kept at a temperature of 45° F. (7° C.) or less

until pasteurized or, if pasteurization is not required, until processed. This paragraph does not apply to unpasteurized grade A milk received at a dairy plant within 2 hours after milking, provided that the unpasteurized milk, after subsequent pasteurization, is held in compliance with par. (d).

(c) Except as provided under par. (e), unpasteurized grade B milk and other grade B dairy products received for processing at a dairy plant shall be kept at a temperature of 50° F. (10° C.) or less until pasteurized or, if pasteurization is not required, until processed. This paragraph does not apply to unpasteurized milk received at a dairy plant within 2 hours after milking, provided that the unpasteurized milk, after subsequent pasteurization, is held in compliance with par. (d).

(d) Except as provided under par. (e), all pasteurized milk and dairy products, after being pasteurized, shall be cooled to a temperature of 45° F. (7° C.) or less and shall then be kept at that temperature at all times. This paragraph does not apply to a grade A cultured dairy product while being cultured, to a dried milk product, or to a grade A dairy product that is sterilized and packaged in a hermetically sealed package.

(e) No milk or dairy product may be held at a dairy plant for more than 4 hours at a temperature that is between 45° F. (7° C.) and 140° F. (60° C.). This paragraph does not apply to any of the following:

1. Grade A cultured dairy products and grade A acidified dairy products while being cultured, provided process controls are monitored and documented by the dairy plant operator in accordance with item 17 (p) of the PMO.

2. Dried dairy products.

3. Butter during micro-fixing.

4. Cheese while being cured, ripened, or tempered for further processing.

5. Pasteurized cream while being ripened for churning into butter.

6. Whey and whey products during the process of crystallization, provided process controls for crystallization of grade A whey and whey products are monitored and documented by the dairy plant operator in accordance with item 17 (p) of the PMO.

7. Acid whey with titratable acidity of not less than 0.40%, expressed as % lactic acid, or a pH of not higher than 4.6.

8. Dairy products that are sterilized and packaged in hermetically sealed packages.

9. Grade B whey originating from pasteurized milk to which one or more starter cultures was added, if the surfaces contacted by that whey have been cleaned and sanitized before holding, transport, and receipt of the whey and the received whey is either pasteurized or cooled to 50° F. or colder not more than 8 hours after its generation at a licensed dairy plant.

(3) PASTEURIZATION. Dairy products shall be pasteurized in compliance with subch. IV.

(4) STORING DAIRY PRODUCTS AND INGREDIENTS. (a) Areas used to store dairy products and ingredients shall be kept in a clean, sanitary, and orderly condition, free from conditions that may adulterate the dairy products or dairy product ingredients.

(b) Dairy products shall be stored at temperatures specified under sub. (2). Other potentially hazardous foods, including potentially hazardous ingredients used in making dairy products, shall be stored at safe temperatures as defined in s. ATCP 65.01 (60).

(c) Dairy products and ingredients shall be stored in an orderly manner, so that storage areas can be easily inspected and cleaned. Dairy products and ingredients may not be stored under conditions that may cause adulteration. Storage areas shall be constructed and maintained so that waste liquids do not accumulate in those areas.

(d) Dairy products and ingredients may not be stored in a manner that may attract or harbor pests. No pesticides or other toxic materials may be stored in a manner that may contaminate dairy products, dairy product ingredients, or packaging materials.

(5) REPROCESSING AND DISPOSAL OF DAIRY PRODUCTS. (a) A dairy plant operator may not reprocess, for use in any dairy product, packaged grade A dairy products that have left the custody of the dairy plant or that have originated from another dairy plant. This does not prohibit any of the following:

1. The use, as ingredients, of packaged dairy products that are specifically manufactured and packaged for use as ingredients in other dairy products.

2. Reprocessing dry milk and dry milk products returned to the dairy plant, provided that the product package is intact.

3. Reprocessing dairy products collected from a packaging defoamer system or drained from processing equipment at the end of a run, if those dairy products are collected and handled in a sanitary manner, held at a temperature of 45° F. (7° C.) or less, and re-pasteurized.

4. Reprocessing specifically authorized in writing by the division, under conditions specified by the division.

(b) A dairy plant operator shall discard any packaged grade A dairy products that are returned to a dairy plant by a wholesaler or retailer. Pending disposal, returned grade A dairy products shall be kept in an area that is clearly designated as a holding area for returned products. The holding area shall be separate from other areas used for the receipt, storage, or processing of dairy products.

(c) A dairy plant operator shall discard all milk and dairy products that have spilled, overflowed, or leaked from equipment, utensils, or packages. This paragraph does not apply to

milk and dairy products caught and collected in a sanitary manner, in equipment specifically designed for that purpose.

(6) DAIRY PRODUCTS INTENDED FOR NON-FOOD USE. Milk and dairy products not intended for human consumption shall be clearly and conspicuously labeled as being not for use as human food. No person may repackage or sell, for use as human food, any milk or dairy products labeled or intended for non-food use.

Note: The manufacture and sale of animal feed is subject to separate licensing and regulation under s. 94.72, Stats.

(7) RECONSTITUTED OR RECOMBINED DAIRY PRODUCTS; PASTEURIZATION. (a) A dairy plant operator shall pasteurize reconstituted or recombined dairy products after those dairy products are reconstituted or recombined, except when the resulting product is exempt from pasteurization under s. ATCP 65.54 (2).

(b) A dairy plant operator may not commingle pasteurized dairy products with unpasteurized milk or dairy products unless the dairy plant operator pasteurizes the resulting product or the resulting product is exempt from pasteurization under s. ATCP 65.54 (2).

(c) A dairy plant operator shall take effective measures to prevent cross contamination between pasteurized and unpasteurized dairy products.

(8) PRESSURIZED AIR AND STEAM; CONTACT WITH DAIRY PRODUCTS. Pressurized air and steam coming in contact with a dairy product or product contact surface shall be clean, safe, and free of contaminants. The system used to generate and supply pressurized air and steam shall comply with applicable "3-A Sanitary Standards" and "3-A Accepted Practices" listed in ch. ATCP 65 APPENDIX A.

Note: The "3-A Sanitary Standards" and "3-A Accepted Practices" listed in APPENDIX A are published by 3-A Sanitary Standards, Inc., 1451 Dolley Madison Boulevard, Suite 210, McLean, VA 22101-3850, telephone (703)790-0295, website www.3-a.org. Copies are on file with the division and the legislative reference bureau. Copies may be purchased from the "3-A Sanitary Standards, Inc. Online Store" at http://www.techstreet.com.

(9) FIRE, FLOOD, OR CALAMITY DAMAGE. If a dairy product or ingredient is subjected to possible contamination in a fire, flood, or other calamity, no person may sell or reprocess that product or ingredient for human consumption unless the division first inspects the product or ingredient and authorizes its sale or reprocessing for human consumption. A dairy plant operator shall notify the division whenever dairy products or ingredients in the operator's possession have been subjected to possible damage or contamination because of fire, flood, or other calamity.

ATCP 65.41 Low-acid or acidified dairy products packaged in hermetically sealed containers for non-refrigerated storage. (1) Manufacturing of low-acid dairy products, that have a pH greater than 4.6 and a water activity greater than 0.85, and are packaged in a hermetically sealed container for non-refrigerated storage, shall be done in compliance with 21 CFR 108.35 and 113.

(2) Manufacturing of acidified dairy products, as defined in 21 CFR 114.3 (b), that are packaged in a hermetically sealed container for non-refrigerated storage, shall be done in compliance with 21 CFR 108.25 and 114.

ATCP 65.42 Recall plan. (1) PLAN REQUIRED. An operator of a dairy plant at which dairy products are manufactured or processed shall prepare a written plan for identifying and recalling milk and dairy products processed at that dairy plant, and any other food processed at the facility, should a recall become necessary. The dairy plant operator shall update the plan as necessary and shall make it available to the division for inspection and copying upon request. This requirement does not apply to the operator of a receiving station or a transfer station.

(2) PLAN CONTENTS. A plan, written pursuant to sub. (1), shall do all of the following:

(a) Identify key individuals or positions that are responsible for planning, approving, and implementing recalls on behalf of the dairy plant operator.

(b) Identify key individuals or entities to be contacted or consulted in connection with a recall.

(c) Include procedures for the routine identification, dating, and tracking of milk and dairy product lots so that in a recall the affected lots can be identified and distinguished from unaffected lots.

(d) Include procedures to enable routine identification, dating, and tracking of milk and dairy product shipments from the dairy plant. Tracking shall identify shipment recipients and contents, cross–referenced to lots, so that in a recall recipients of affected lots can be contacted.

(e) Include procedures for determining the nature and scope of a recall, including affected milk and dairy product lots, shipments, and shipment recipients.

(f) Include procedures for identifying and communicating with affected persons, including suppliers, milk and dairy product shipment recipients, down-line buyers, consumers, government agencies, and others.

(g) Identify potential target audiences for recall information, including consumers, distributors, and government agencies.

(h) Identify potential methods for communicating with target audiences, under par. (g).

(i) Identify key information, including the identity of the affected milk and dairy products, the reason for the recall, and suggested actions to be taken by affected persons, that may be necessary to communicate to affected persons in a recall.

ATCP 65.44 Dairy plant records. (1) MANDATORY RECORDS. A dairy plant operator, including a milk contractor that submits a milk producer license application on behalf of a milk producer and thereby certifies that the milk producer's dairy farm and milking operations comply with applicable requirements under this chapter, shall keep all of the following records, as

applicable to their operation, and shall retain those records for the period of time specified under this subsection:

(a) Records related to milk receipts and producer payrolls, as required by s. ATCP 100.32 (1). Records under this paragraph shall include milk collection records received from bulk milk weighers and samplers under s. ATCP 82.10 (10). Records under this paragraph shall be retained for at least 3 years.

(b) Records of all dairy product ingredients received at the dairy plant, including the sources from which the ingredients were received. Records under this paragraph shall be retained for at least two years.

(c) Daily records of all finished products produced at the dairy plant. Records under this paragraph shall be retained for at least one year.

(d) Records of all milk quality tests and sediment tests conducted on milk shipments received by the dairy plant operator, including but not limited to tests required under subch. V. Records under this paragraph shall be retained for at least 2 years.

(e) Records of all in-plant tests, performed by a dairy plant operator on milk and dairy products held or processed by the dairy plant operator, to determine bacterial counts or identify possible adulteration of that milk or those dairy products. Records under this paragraph shall be retained for at least 2 years.

(f) Records of private water supply tests, if any, conducted under s. ATCP 65.24 (8). Records under this paragraph shall be retained for at least 2 years.

(g) Cleaning and sanitizing records for all C-I-P systems, as required under s. ATCP 65.30. (2) (b). Records under this paragraph shall be retained for at least 2 years. Records may be

stored in electronic form, with or without hard copy printouts, if the electronic records are readily accessible by a division representative.

(h) A record of every calibration, daily performance check, daily reference check, and hourly reference check performed on a milkfat or protein testing device, as required by s. ATCP 65.84 (10). Records under this paragraph shall be retained for at least one year.

(i) Pasteurization records required under s. ATCP 65.66. Records under this paragraph shall be retained for at least 2 years.

(j) Cleaning and sanitizing records for bulk milk tankers cleaned and sanitized at a dairy plant, as required under s. ATCP 82.08 (4). Records under this paragraph shall be retained for at least 15 days.

(k) Temperature monitoring records made by the dairy plant operator, including records of dairy product temperatures, storage temperatures, and processing temperatures. Records under this paragraph shall be retained for at least 2 years.

(L) Inventory control records for vitamin fortification of fluid milk products, including vitamins used and the quantity of fortified fluid milk products produced. Records under this paragraph shall be retained for at least 2 years.

(m) Vitamin assay test results conducted on fortified dairy products under s. ATCP 65.74 (4). Records under this paragraph shall be retained for at least 2 years.

(n) Cleaning and sanitizing records required under s. ATCP 65.28 (7) (g). Records under this paragraph shall be retained for at least 2 years.

(o) Bills of lading or other shipping documents relating to the bulk shipment of dairy products from the dairy plant to another dairy plant, or to the dairy plant from another dairy

plant. The dairy plant operator shall retain each shipping document for at least 3 years. Each shipping document shall include all of the following information:

1. The name, address, and license number of the dairy plant from which the shipment originates. If the dairy product is a grade A dairy product, the shipping document shall also include the dairy plant shipper identification number assigned under the PMO.

2. If grade A milk or dairy product was shipped in a bulk milk tanker, the bulk milk tanker grade A permit identification number, assigned under ch. ATCP 82 or the PMO, and the seal number on the bulk milk tanker inlet, outlet, wash connections, and vents.

3. The name of the dairy product shipped.

4. The weight of the dairy product shipped.

5. The temperature of the dairy product when loaded for shipment.

6. The date of shipment.

7. The name of the dairy regulatory agency at the shipment point of origin.

8. Whether the dairy product was raw, pasteurized, or treated with heat to an extent less than pasteurization.

9. The grade of product.

(p) Milk producer affidavits certifying that the milk producers do not use bovine somatotropin, as required under ss. ATCP 83.02 (5) and (7).

(2) ACCESSIBILITY OF RECORDS; ELECTRONIC RECORDS. Records under sub. (1) shall be kept at the dairy plant or, for records kept by a milk contractor that submits a milk producer license application on behalf of a milk producer and thereby certifies that the milk producer's dairy farm and milking operations comply with applicable requirements under this chapter, at the milk contractor's business location, and shall be made available to the division for inspection and

copying upon request. Records may be kept in electronic form, with or without hard copy printouts, if the electronic records are readily accessible to a division representative and comply with the applicable provision of Appendix H, sections IV and V of the PMO.

ATCP 65.46 Dairy plant reports to department. **(1)** REPORTS RELATED TO LICENSES, PERMITS, FINANCIAL STATEMENTS AND MILK QUALITY. A dairy plant operator, including a milk contractor that submits a milk producer license application on behalf of a milk producer and thereby certifies that the milk producer's dairy farm and milking operations comply with applicable requirements under this chapter, shall submit all of the following reports to the department:

(a) Reports required for the issuance or annual renewal of a dairy plant license or grade A permit under s. ATCP 65.02.

(b) Financial statements and reports required as part of an application for a milk contractor license under ch. ATCP 100, if any.

(c) Monthly milk quality test reports required under subch. V and dairy farm inspection reports required as part of a milk producer or grade A producer permit application under ss. ATCP 65.910 and 65.912.

(2) REPORTS RELATED TO RESULTS OF PRODUCT TESTING FOR MICROBIAL PATHOGENS OR TOXINS. (a) Except as provided in par. (b), a dairy plant operator shall report to the division the result of any microbiological test or laboratory analysis that confirms the presence of a pathogenic organism or toxin in a ready-to-eat dairy product produced by the operator. The operator shall report to the division within 24 hours after the operator obtains the test result. The operator may report orally, electronically, or in writing.

(b) A dairy plant operator is not required to report a test result under par. (a) if all the following apply:

1. The ready-to-eat dairy product is identified by a product code or production lot number and remains under the control or custody of the dairy plant operator.

2. The operator does not sell or distribute any ready-to-eat dairy product that bears the product code or production lot number under subd. 1.

ATCP 65.48 Confidential information. (1) None of the following information, received by the department from a dairy plant operator, including a milk contractor that submits a milk producer license application on behalf of a milk producer and thereby certifies that the milk producer's dairy farm and milking operations comply with applicable requirements under this chapter, is subject to public inspection under s. 19.35, Stats.

(a) Financial information protected from disclosure under s. 126.84 (1) (a), Stats.

(b) Information qualifying as a trade secret as defined in s. 134.90 (1) (c), Stats.

(2) None of the following information received by the department from a dairy plant operator, including a milk contractor that submits a milk producer license application on behalf of a milk producer and thereby certifies that the milk producer's dairy farm and milking operations comply with applicable requirements under this chapter, is subject to public inspection under s. 19.35, Stats., unless the department determines that inspection is necessary to protect the public health, safety, or welfare:

(a) Information that identifies individual milk producers who deliver milk to the dairy plant operator, or sell milk to a milk contractor, if the information is in the form of a composite list identifying those producers with that dairy plant operator or milk contractor, except as provided under s. 126.70 (6) (b) and (c), Stats.

Note: See s. 97.20 (3m), Stats.

(b) Information pertaining to individual milk producer production and milk quality records if that information identifies the producer.

Note: See s. 97.22 (10), Stats.

ATCP 65.50 Dairy product labeling. (1) GENERAL. Dairy product labeling shall comply with applicable requirements in ch. 97, Stats., this chapter, and chs. ATCP 81, 83, 85, and 90.

(2) PRODUCTS NOT FOR HUMAN CONSUMPTION. No dairy plant operator may distribute any dairy product manufactured by that dairy plant operator unless any of the following applies:

(a) The dairy product complies with, and has been produced according to, this chapter and ch. ATCP 82.

(b) The dairy product is prominently labeled as animal feed according to ch. ATCP 42.

(c) The dairy product is prominently labeled as "NOT FOR HUMAN FOOD OR ANIMAL FEED" and is sold only for non-food and non-feed purposes. The label shall include the manufacturer's name and address and the address of the location where the product was manufactured. The label may not include any dairy plant license or identification number issued by the department.

SUBCHAPTER IV

PASTEURIZATION

ATCP 65.52 Unpasteurized milk sales prohibited; exemptions. No person may sell or distribute unpasteurized milk or dairy products to consumers or to any person for resale or redistribution in unpasteurized form to consumers. This section does not prohibit any of the following:

(1) The sale or distribution of milk or dairy products that are heat sterilized in hermetically sealed containers.

(2) The distribution of unpasteurized fluid milk, produced on a dairy farm, to any of the following:

(a) The milk producer who is licensed under s. ATCP 65.02 (1) to operate that dairy farm, and who, as license holder, assumes legal responsibility for dairy farm and milking operations.

(b) An individual who has a bona fide ownership interest in the dairy farm and milking operation under par. (a), if the milk producer operating the dairy farm and milking operation is a legal entity other than an individual or married couple.

(c) A family member or nonpaying household guest who consumes the milk at the home of an individual milk producer or bona fide owner under par. (a) or (b).

(3) The sale or distribution of unpasteurized milk, produced on a dairy farm, to the employees of that dairy farm.

(4) The incidental sale of unpasteurized milk to a consumer at the dairy farm where the milk is produced. A sale is not incidental if the consumer subsequently sells the milk or distributes the milk, other than distribution for consumption by the consumer, the consumer's family, or the consumer's nonpaying household guests. A sale is not incidental if it is made in the regular course of business, or is preceded by any advertising, offer or solicitation made to the general public through any communications medium.

ATCP 65.54 Pasteurization required. (1) Except as provided under sub. (2), every dairy product shall be pasteurized at the dairy plant where that dairy product is manufactured.

(2) Subsection (1) does not apply to any of the following:

(a) A dairy product shipped in bulk to another dairy plant for use in manufacturing dairy products, provided that the shipment is accompanied by a bill of lading that identifies the dairy product as unpasteurized.

(b) A dairy product made entirely from dairy products that have been pasteurized at the same dairy plant.

(c) Ice cream or frozen dessert made from pasteurized ice cream mix or pasteurized frozen-dessert mix, provided that no unpasteurized dairy product is added to the pasteurized mix.

(d) A dairy product for which the standard of identity provides that the dairy product and its ingredients need not be pasteurized.

(e) A dairy product that is sterilized and packaged in a hermetically sealed package.

(f) Cream, skim milk, or low-fat milk that have been treated with heat to an extent less than pasteurization, and then shipped in bulk to another dairy plant for use in manufacturing dairy products, provided that the bulk shipment is accompanied by a bill of lading that identifies the contents of the bulk shipment as being unpasteurized and heat-treated. The heat-treated cream, skim milk, or low-fat milk may be heated not more than once for separation purposes, to a temperature that is not less than 125° F. (52° C.) nor more than 161° F. (72° C.). Heat-treated cream may be heated to a greater extent, up to a temperature of 166° F. (75° C.) in a continuing heating process, if further heating is necessary to deactivate enzymes for functional reasons. Cream, skim milk, and low-fat milk, after being heated to an extent less than pasteurization, shall immediately be cooled to a temperature of 45° F. (7° C.) or less.

(g) Dried condensed whey produced by drying condensed whey that was previously pasteurized at another dairy plant, provided that all of the following apply:

1. The pasteurized condensed whey received for drying contained at least 40% total solids, and was partially crystallized by cooling at the dairy plant where it was pasteurized.

2. The partially crystallized condensed whey was kept at a temperature of 45° F. (7° C.) or less prior to drying.

3. The bulk milk tanker used to transport the partially crystallized condensed whey was washed and sanitized immediately before filling, was sealed immediately after filling, and remained sealed until it was unloaded at the receiving dairy plant.

4. The receiving dairy plant unloaded the partially crystallized condensed whey using unloading pumps and pipelines that are used only for that purpose and have been cleaned and sanitized as a separate C-I-P circuit before use in unloading.

(h) Grade B dairy products produced by adding previously pasteurized and dried dairy products with a water activity not greater than 0.85 to previously pasteurized grade B dairy products, if approved in writing by the division.

(i) Grade B dairy products produced by adding previously pasteurized packaged dairy products to previously pasteurized grade B dairy products, if approved in writing by the division.

(3) A dairy product, required to be pasteurized under sub. (1), shall be pasteurized by, or under the direct supervision of, a pasteurizer operator who has successfully completed any of the following:

(a) A pasteurization training course, of at least 8 hours duration, provided by the University of Wisconsin or an equivalent course approved by the division.

(b) A competency examination approved by the division.

(4) If a dairy product standard of identity requires that any ingredient of that product be pasteurized, the ingredient shall be pasteurized according to s. ATCP 65.58.

(5) Except as provided in subs. (6) to (8), a dairy product that is required to be pasteurized under sub. (1) or (4) shall be pasteurized before it is introduced into any membrane or condensing processing system.

(6) Subsection (5) does not apply to grade B whey or whey product if at least one of the following applies:

(a) The whey or whey product is derived from milk pasteurized in the same dairy plant.

(b) The whey is acid whey, which has a pH less than 4.7 when drawn from the curd.

(c) The whey or whey product is processed in a membrane processing system that complies with sub. (9) and is designed and maintained to keep the whey or whey product at a temperature of 65° F. (18.3° C.) or below during processing. If the whey or whey product temperature exceeds 65° F. (18.3° C.) for more than 15 minutes during processing, or exceeds 70° F. (21.1° C.) at any time during processing, the whey or whey product shall be immediately diverted from moving beyond the membrane processing system by means of automatic controls. The diverted product shall be treated in one of the following ways:

1. Recycled through the membrane processing system and subjected to cooling. The diverted product may proceed beyond the membrane processing system when the product temperature falls to 65° F. (18.3 ° C.) or below.

2. Cooled in a system other than the membrane processing system until the temperature falls to 45° F. (7° C.) or below, and may then be reintroduced into the membrane processing system.

3. Pasteurized in a pasteurization system, and may then be reintroduced into the membrane processing system.

4. Discarded.

(7) Subsection (5) does not apply to grade A whey or whey product that is pasteurized in a membrane processing system that complies with sub. (9) if at least one of the following apply:

(a) The whey is acid whey, which has a pH less than 4.7 when drawn from the curd.

(b) The membrane processing system is designed and maintained to keep the whey or whey product at a temperature of 45° F. (7° C.) or below during processing.

(8) Subsection (5) does not apply to unpasteurized milk that is processed, before pasteurization, in a membrane processing system that complies with sub. (9) and is designed and maintained to keep the milk at a temperature of 65° F. (18.3° C.) or below during processing. If the milk temperature exceeds 65° F. (18.3 ° C.) for more than 15 minutes during processing, or exceeds 70° F. (21.1° C.) at any time during processing, the milk shall be immediately diverted from moving beyond the membrane processing system by means of automatic controls. The diverted milk shall be treated in any of the following ways:

(a) Recycled through the membrane processing system and subjected to cooling. The diverted product may proceed beyond the membrane processing system when the product temperature falls to 65° F. (18.3° C.) or below.

(b) Cooled in a system other than the membrane processing system until the temperature falls to 45° F. (7° C.) or below, and may then be reintroduced into the membrane processing system.

(c) Pasteurized in a pasteurization system, and may then be reintroduced into the membrane processing system.

(d) Discarded.

(9) A membrane processing system under sub. (6) (c), (7), or (8) shall be equipped with temperature monitoring and recording devices that comply with Appendix H, Subsection IV of the PMO. At a minimum, the system shall monitor and record product temperature at all of the following points during processing:

(a) The point at which the dairy product enters the system.

(b) A point immediately preceding each intermediate cooling.

(c) A point immediately preceding final cooling.

(d) The point at which the product exits the system.

Note: PMO Appendix H, Subsection IV is on file with the division and the legislative reference bureau. Copies may be obtained from the division at cost or online at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk.

ATCP 65.56 Labeling pasteurized and unpasteurized products (1) If a dairy product is pasteurized or made exclusively from pasteurized ingredients, the label on every shipping container of that dairy product shall clearly and conspicuously state that the product is "pasteurized" or "UHT pasteurized," as appropriate. Every label under this subsection shall also include the name and address, or the unique identification number, of the dairy plant where the dairy product was pasteurized.

(2) Except as provided under sub. (3) or (4), if a dairy product is not pasteurized or made exclusively from pasteurized ingredients, the label on every shipping container and consumer package of that dairy product shall state that the product is unpasteurized.

(3) Subsection (2) does not apply to cheese that meets all of the following requirements:

(a) The standard of identity for the cheese provides that the cheese may be made from unpasteurized dairy products.

(b) The cheese is held for at least 61 days at a temperature not less than 35° F. before being distributed for retail sale, or for further processing without pasteurization.

(c) The label on every shipping container and consumer package of cheese states that the cheese is "aged over 60 days."

(4) Subsection (2) does not apply to a dairy product that is sterilized and sealed in a hermetically sealed container.

Note: See dairy product labeling requirements in subch. III.

ATCP 65.58 Pasteurization time and temperature (1) If a dairy product is required to be pasteurized under s. ATCP 65.54, the dairy product shall be pasteurized according to this subchapter unless the division authorizes in writing a different but equally effective pasteurization system or method. Alternative times and temperatures for pasteurizing grade A milk and milk products shall be recognized by the United States food and drug administration. All of the dairy product shall be heated to the required temperature and continuously held at or above the required temperature for the required period of time. Pasteurization equipment shall be equipped with accurate measuring, recording, and control devices, as required by ss. ATCP 65.60 and 65.62, to ensure that the time and temperature requirements under this section are met.

(2) Dairy products identified in table 2, unless UHT pasteurized under sub. (3), shall be pasteurized in a batch pasteurizer tested in accordance with s. ATCP 65.68 or HTST pasteurizer tested in accordance with s. ATCP 65.68 at or above the temperature specified in the table for at least the length of time specified in the table.

Table 2
Pasteurization Requirements for Selected Dairy Products

	Product Group	Batch Pasteurization	HTST Pasteurization
(a)	Milk, skim milk, or buttermilk	145°F. (63° C.) for 30 minutes	161°F. (72°C.) for 15 seconds
(b)	Cream, fluid dairy products, or blends of those products	150°F. (66° C.) for 30 minutes	166°F. (75°C.) for 15 seconds
(c)	Cream for butter	165°F. (74°C.) for 30 minutes	185°F. (85° C.) for 15 seconds
(d)	High total solids products (>18%)	150°F. (66° C.) for 30 minutes	166° F. (75° C.) for 15 seconds
(e)	Frozen-dessert mixes	155° F. (69°C.)	175°F. (80°C.)

	for 30 minutes	for 25 seconds or 180° F. (83°C.) for 15 seconds
(f) Egg nog	155° F. (69°C.) for 30 minutes	175° F. (80° C.) for 25 seconds or 180° F. (83°C.) for 15 seconds
(g) Process cheese	150°F. (66° C.) for 30 seconds	_

(3) A dairy plant operator may use an HHST pasteurizer as an alternative to an HTST pasteurizer. An HHST pasteurizer shall heat and hold a dairy product at one of the following temperatures for the corresponding length of time:

(a) 191° F. (89° C.) for 1.0 sec.

(b) 194° F. (90° C.) for 0.5 sec.

(c) 201° F. (94° C.) for 0.1 sec.

(d) 204° F. (96° C.) for 0.05 sec.

(e) 212° F. (100° C.) for 0.01 sec.

(4) A UHT pasteurized dairy product shall be thermally processed at or above a temperature of 280° F. (138° C.) for at least 2 seconds.

ATCP 65.60 Batch pasteurization. Batch pasteurization equipment shall be of the non-coil type. Batch pasteurization equipment shall be constructed and operated so that pasteurization complies with item 16p (A) of the PMO and with applicable "3-A Sanitary Standards" and "3-A Accepted Practices" listed in ch. ATCP 65 Appendix A. Thermometers shall be constructed and operated in compliance with Appendix H, item IV of the PMO. The temperature of the air space above the pasteurized product shall be at least 5° F. (3° C.) higher than the minimum pasteurization temperature of the pasteurized product.

Note: The "3-A Sanitary Standards" and "3-A Accepted Practices" listed in Appendix A are published by 3-A Sanitary Standards, Inc., 1451 Dolley Madison Boulevard, Suite 210, McLean, VA 22101-3850, telephone (703) 790-0295, website www.3-a.org. Copies are on file with the division and the legislative reference bureau. Copies may be purchased from the "3-A Sanitary Standards, Inc. Online Store" at http://www.techstreet.com. Copies of the PMO are on file with the division and the legislative reference bureau. Copies may be obtained from the division at cost or are available online at

ATCP 65.62 HTST and HHST pasteurization. Pasteurization by means of HTST or HHST pasteurization shall comply with the standards set forth in "3-A Accepted Practices for the Sanitary Construction, Installation, Testing and Operation of High-Temperature Short-Time and Higher Heat Shorter Time Pasteurizer Systems," standard 3A 603-07 (November, 2005), published by 3-A Sanitary Standards, Inc.

Note: Copies of the "3-A Accepted Practices for the Sanitary Construction, Installation, Testing, and Operation of High-Temperature Short-Time and Higher Heat Shorter Time Pasteurizer Systems," standard 3A 603-07 (November, 2005) are on file with the division and the legislative reference bureau. Copies may be obtained from the "3-A Sanitary Standards, Inc. Online Store" at http://www.techstreet.com.

ATCP 65.64 Aseptic processing and packaging. (1) GRADE A REQUIREMENTS. Grade A aseptic processing and packaging systems shall comply with standards specified in items 16p (B), (C), and (D) of the PMO and with applicable standards specified in 21 CFR 108.25, 108.35, 113 and 114.

(2) GRADE B REQUIREMENTS. Grade B aseptic processing and packaging systems shall comply with applicable standards specified in 21 CFR 113 and 21 CFR 114.

Note: The PMO is on file with the division and the legislative reference bureau. Copies may be obtained from the division at cost or online at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk.

ATCP 65.66 Pasteurization records. (1) GENERAL. A dairy plant operator shall keep pasteurization records for all dairy products pasteurized by the operator. Records shall cover all types of pasteurization operations, including batch operations, HTST operations, and HHST operations. Records shall comply with this section. The department shall review pasteurization records as part of each routine inspection of a dairy plant.

(2) BATCH PASTEURIZATION RECORDS. Except as provided in sub. (3), batch pasteurization records shall include all the following:

(a) Each date, including the year, on which dairy products are pasteurized.

(b) The identification number or location of each pasteurization time and temperature recording chart, if more than one is used.

(c) A continuous temperature recording chart temperature record for each batch of pasteurized product.

(d) The pasteurization holding time, as shown on the temperature recording chart, for each batch of pasteurized product. Records shall include filling and emptying times, if applicable.

(e) The temperature reading on the airspace thermometer at the start and end of the pasteurization holding period, and at specific times identified as points on the temperature recording chart.

(f) The temperature reading on the indicating thermometer at the start of the pasteurization holding period, and at a specific time identified as a point on the temperature recording chart.

(g) The name and quantity of dairy product included in each pasteurization batch shown on the temperature recording chart.

(h) A record of any unusual circumstances that occurred during each batch pasteurization.

(i) The name of the dairy plant.

(j) The signature or initials of the dairy plant operator, or a responsible employee or agent of the operator.

(3) HTST AND HHST PASTEURIZATION RECORDS. Pasteurization records for HTST and HHST pasteurization operations shall include all the following:

(a) Each date, including the year, on which dairy products are pasteurized.

(b) The identification number or location of each pasteurization time and temperature recording chart, if more than one is used.

(c) A continuous temperature recording chart for each pasteurization run.

(d) The temperature reading on the indicating thermometer at the start of each pasteurization run, and at a specific time identified as a point on the temperature recording chart.

(e) Documentation, on the temperature recording chart, of every time period during which the flow-diversion device on the pasteurizer is in the forward-flow position.

(f) The cut-in and cut-out product temperatures at the beginning of each HTST pasteurization run. The pasteurizer operator shall record these temperatures daily on the temperature recording chart.

(g) The temperature reading on the indicating thermometer whenever the temperature recording chart for the pasteurization system is changed.

(h) The name and quantity of dairy product included in each pasteurization run shown on the temperature recording chart.

(i) A record of any unusual circumstances that occurred during each pasteurization run.

(j) The name of the dairy plant.

(k) The signature or initials of the dairy plant operator, or a responsible employee or agent of the operator.

(4) FLOW RECORDS FOR HTST AND HHST PASTEURIZERS WITH METER BASED TIMING SYSTEMS. In addition to requirements in sub. (3), pasteurization records for HTST and HHST pasteurization operations with meter based timing systems shall include all of the following:

(a) Each date, including the year, on which dairy products are pasteurized.

(b) The identification number or location of each pasteurization time and flow-rate recording chart, if more than one is used.

(c) A continuous flow-rate recording chart record of the flow rate.

(d) A continuous flow-rate recording chart record of the status of the high and low flow/loss of signal alarms.

(e) The name and quantity of dairy product pasteurized in each pasteurization run shown on the flow-rate recording chart.

(f) A record of any unusual circumstances that occurred during each pasteurization run.

(g) The name of the dairy plant.

(h) The signature or initials of the dairy plant operator or a responsible employee or agent of the operator.

ATCP 65.68 Pasteurizer testing. (1) GENERAL. The division shall test and seal pasteurization systems according to this section. Except as provided under sub. (6), no person may use any pasteurization system to pasteurize grade A or grade B dairy products unless that system bears the unbroken seals applied by the department under sub. (5).

(2) TEST PROCEDURE. The division shall test grade A and grade B pasteurization systems according to the procedure specified in Appendix I of the PMO.

Note: PMO Appendix I is on file with the division and the legislative reference bureau. Copies may be obtained from the division at cost or online at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk.

(3) TEST FREQUENCY; GRADE A PASTEURIZERS. The division shall test each grade A pasteurization system at the following times:

(a) Before the pasteurization system is first put into operation.

(b) At least once every 3 months, except that a holding time test may be conducted at least once every 6 months.

(c) Whenever a seal, under sub. (5), is broken.

(4) TEST FREQUENCY; GRADE B PASTEURIZERS. The division shall test a grade B pasteurization system at the following times:

(a) Before the pasteurization system is first put into operation.

(b) At least once every 12 months.

(c) Whenever a seal, under sub. (5), is broken.

(5) DEPARTMENT SEALS. When the division's test confirms that a pasteurization system is operating correctly, the division shall apply seals that prevent any alteration of the system that would allow any unpasteurized milk or dairy product to flow through the system.

(6) BROKEN SEAL. (a) A dairy plant operator shall notify the division by telephone, electronic mail, or facsimile (FAX) transmission within 2 hours after the dairy plant operator breaks a seal applied by the division under sub. (5), or within 2 hours after a pasteurizing system malfunctions to the possible detriment of public health or safety. The dairy plant operator shall also notify the department in writing, on a form provided by the division, within 5 business days after the seal is broken or the system malfunctions.

(b) A dairy plant operator may not operate a pasteurizer after breaking a seal applied by the department under sub. (5), unless all of the following conditions are met:

1. The dairy plant operator notifies the department under par. (a).

2. The dairy plant operator determines and documents that pasteurization time and temperature requirements under s. ATCP 65.58 are met, and that the pasteurization system is repaired and functioning properly. Time and temperature records required by s. ATCP 65.66 shall be retained for at least 6 months.

3. The dairy plant operator conducts phosphatase tests, under par. (d), if the pasteurizer is used to pasteurize milk without added flavors or ingredients other than vitamins. Phosphatase testing shall confirm that pasteurized milk without added flavors or ingredients other than vitamins contains less than 350 milli-units of detectable alkaline phosphatase per liter.

4. A pasteurizer operator qualified under s. ATCP 65.54(3) is present to operate the pasteurizer, or to supervise its operation.

(c) A dairy plant operator may not operate a pasteurizer for more than 10 calendar days after breaking a seal applied by the department under sub. (5), unless any of the following occurs:

1. The division tests the pasteurizer and replaces the broken seal.

2. A dairy plant operator or employee certified under sub. (7), tests the pasteurizer and replaces the broken seal on an interim basis, pending retesting and resealing by the department.

(d) Phosphatase testing, under par. (b) 3., shall comply with all of the following requirements:

1. The dairy plant operator shall collect and analyze a test sample, directly from the pasteurizer system, at least once during every 4 hours of pasteurizer operations.

2. The dairy plant operator shall store each test sample at a temperature below 45° F. (7° C.) until it is tested and shall analyze each sample within 48 hours after it is collected.

3. The dairy plant operator shall analyze each sample using the Fluorophos ALP method, the Charm Paslite Alkaline Phosphatase method, or another test method approved in writing by the division.

4. Tests shall be performed by an individual who is trained to conduct phosphatase tests on milk. If the dairy plant is a grade A dairy plant, tests shall be performed by a laboratory that the department has certified under ch. ATCP 77 or the PMO.

(7) EMERGENCY TESTING AND SEALING. (a) The division may certify a dairy plant operator or employee to test and seal a pasteurization system in that dairy plant on an emergency basis under par. (b). To be certified under this paragraph, a dairy plant operator or employee shall have successfully completed a training course approved by the division. The division may suspend or revoke certification for cause.

(b) A dairy plant operator or employee certified under par. (a) may test and seal a pasteurization system in that dairy plant on an emergency basis, pending retesting and resealing by the division, under par. (c), if emergency testing and sealing is necessary to continue pasteurizing operations after the department's seal is broken. Testing under this paragraph shall comply with the procedure specified under sub. (2).

(c) The division shall promptly retest and reseal a pasteurization system after the division receives notice, under sub. (6) (a), that its seal applied to that system has been broken. The division shall retest and reseal a pasteurization system, under this paragraph, regardless of whether the pasteurization system has been tested and sealed under par. (b). The division need not retest or reseal a pasteurization system that is withdrawn from service.

SUBCHAPTER V

SAFETY AND QUALITY STANDARDS

ATCP 65.70 Milk quality standards for milk collected from a dairy farm. Milk received or collected from a dairy farm shall comply with all of the following standards at the time of receipt or collection:

(1) ADULTERATION AND ODORS. The milk shall not be visibly or otherwise adulterated, have any objectionable odor, or be abnormal in appearance or consistency.

(2) BACTERIAL COUNT. (a) *Limits.* The bacterial count of grade A milk, as determined by a standard plate count, plate loop count or other method approved by the division under this subchapter, shall not exceed 100,000 per ml. The bacterial count of grade B milk shall not exceed 300,000 per ml. Except as provided under par. (f), a dairy plant operator is not required to reject milk shipments in response to a violation of this subsection unless the division suspends or revokes the milk producer's license or grade A producer permit, or issues an order affecting the milk shipments under s. ATCP 65.927.

(b) *Monthly testing required.* During every month in which a dairy plant operator or a milk contractor licensed as a dairy plant receives milk from a milk producer, the dairy plant operator shall perform at least one standard plate count (SPC) or plate loop count (PLC) on a milk sample obtained from the producer under s. ATCP 82.12. A dairy plant operator shall perform tests under this section and s. ATCP 65.76 on the same milk samples.

(c) *New milk producer; initial testing.* A dairy plant operator or a milk contractor licensed as a dairy plant shall perform a SPC or PLC on a milk sample collected from the first milk shipment received from a milk producer. The dairy plant operator shall report the test result to the department and the milk producer within 7 days after the dairy plant operator obtains the test result.

(d) *Monthly reporting.* For each month in which a dairy plant operator or milk contractor licensed as a dairy plant receives milk from a milk producer, the dairy plant operator shall report to the division and the milk producer at least one representative test result under par. (b) for a milk shipment procured in that month. The dairy plant operator shall report the test result within 7 days after the operator obtains the test result.

(e) *Representative test results.* A test result is not representative, for reporting purposes under this subsection unless all the following apply:

1. The dairy plant operator collects the test sample according to a uniform sampling schedule that the operator applies to all milk producers who ship milk to the operator's dairy plant.

2. The dairy plant operator reports the test result according to standard reporting criteria that the operator applies to all milk producers who ship milk to the dairy plant operator's dairy plant.

(f) *Immediate response level; reporting and follow-up.* If a bacterial count under this section or s. ATCP 65.76 exceeds 750,000 per ml., the dairy plant operator shall do all the following:

1. Report the test result to the division and the milk producer within 3 business days after the operator obtains the test result.

2. Perform a confirmatory bacteriological test on at least one more sample of milk collected from the milk producer's dairy farm. The dairy plant operator shall collect the confirmatory sample within 14 days after the date on which the dairy plant operator collected the original sample. The dairy plant operator shall report the confirmatory test result to the division and the milk producer within 3 business days after the operator obtains the test result.

3. Reject milk shipments from the dairy farm if the confirmatory test shows a bacterial count in excess of 750,000 per ml. The milk producer may not ship milk from the dairy farm to any dairy plant until a dairy plant operator conducts another test and finds that milk from the farm has a bacterial count not more than 750,000 per ml.

(g) *Division inspection; reinspection fee.* The division may inspect a dairy farm in response to any bacterial count reported to the division under this section. If the division inspects a dairy farm in response to a confirmatory bacterial count of more than 750,000 per ml. under par. (f), the division shall charge a reinspection fee under s. ATCP 65.02 (19). The division may not

charge a reinspection fee if the confirmatory bacterial count does not exceed 750,000 per ml., or if the division inspects more than 3 weeks after the division receives the confirmatory bacterial count.

Note: Under s. ATCP 65.920 the department will suspend a producer's grade A farm permit if 3 of the last 5 bacterial counts reported to the department under this section exceed the grade A standard of 100,000 per ml. under s. ATCP 65.70 (2). The department will suspend the producer's grade A permit regardless of whether any bacterial count exceeds the immediate response level of 750,000 per ml. under this section.

Note: Under s. ATCP 65.920 the department may suspend a milk producer's license if bacterial counts continue to exceed the grade B standard of 300,000 per ml. under s. ATCP 65.70 (2). The department may suspend the producer's license regardless of whether any bacterial count exceeds the immediate response level of 750,000 per ml. under this section. If 2 of the last 4 bacterial counts reported to the department under this section exceed the grade B standard of 300,000 per ml., the department will, at a minimum, send a warning notice to the producer.

(h) *Laboratory reporting.* A laboratory that performs tests under this section for a dairy plant operator may report the test results for the dairy plant operator.

(i) *Electronic reporting.* A dairy plant operator or laboratory shall report test results under this section in an electronic form approved by the division.

(3) DRUG RESIDUES. The milk shall not contain any drug residue. A dairy plant operator or milk contractor licensed as a dairy plant shall test each load of milk received from each milk producer for drug residues in accordance with s. ATCP 65.72.

(4) SOMATIC CELL COUNT. (a) *Limits.* The somatic cell count of cow or sheep milk, as determined by a direct microscopic somatic cell count, an electronic somatic cell count, or other method approved by the division under this subchapter, shall not exceed 750,000 cells per ml. The somatic cell count of goat milk, as determined by the Pyronin Y Methyl green stain test, shall not exceed 1,500,000 cells per ml. Except as provided under sub. (g), a dairy plant is not required to reject milk shipments in response to a violation of this subsection unless the department suspends or revokes the milk producer's license or grade A producer permit, or issues an order affecting the milk shipments under s. ATCP 65.927.

(b) *Monthly Testing Required.* During every month in which a dairy plant operator or milk contractor licensed as a dairy plant receives milk from a milk producer, the dairy plant operator shall perform at least one somatic cell count on a milk sample obtained from the producer under s. ATCP 82.12. If the dairy plant operator tests more than one milk sample each month, the dairy plant operator shall collect the samples at regular intervals throughout the month. A dairy plant operator shall perform tests under this subsection and s. ATCP 65.76 on the same milk samples.

Note: Somatic cell tests must be performed using methods prescribed under s. ATCP 65.78 (3). The maximum time between sample collection and testing depends on the test method used.

(c) *New milk producer; initial testing.* A dairy plant operator or milk contractor licensed as a dairy plant shall perform a somatic cell count on a milk sample collected from the milk shipment received from a milk producer. The operator shall report the test result to the division and the producer within 7 days after the operator obtains the test result.

(d) *Test methods.* A somatic cell count under this subsection shall be a direct microscopic somatic cell count or an electronic somatic cell count. If the somatic cell count on goat milk exceeds 1,500,000 per ml., the somatic cell count shall be confirmed using the Pyronin Y Methyl green stain test, unless that test was used to obtain the initial count.

(e) *Monthly reporting.* For each month in which a dairy plant operator or milk contractor licensed as a dairy plant receives milk shipments from a milk producer, the dairy plant operator shall report to the division and the producer at least one representative somatic cell count under sub. (4) for a milk shipment procured in that month. The dairy plant operator shall report the somatic cell count within 7 days after the dairy plant operator obtains the count.

(f) *Representative somatic cell counts.* A somatic cell count is not representative, for reporting purposes under sub. (4), unless all the following apply:

1. The dairy plant operator collects the test sample according to a uniform sampling schedule that the dairy plant operator applies to all milk producers who ship milk to the same dairy plant.

2. The dairy plant operator reports the somatic cell count according to standard reporting criteria that the dairy plant operator applies to all milk producers who ship milk to the same dairy plant.

(g) *Immediate response level; reporting and follow-up.* If a somatic cell count under this section exceeds 1,000,000 per ml. for cow or sheep milk, the dairy plant operator shall do all the following:

1. Report the somatic cell count to the division and the milk producer within 3 business days after the operator obtains the somatic cell count.

2. Perform a confirmatory somatic cell count on at least one more sample of milk collected from the milk producer's dairy farm. The dairy plant operator shall collect the confirmatory sample within 14 days after the date on which the operator collected the original sample. The dairy plant operator shall report the confirmatory somatic cell count to the division and the milk producer within 3 business days after the dairy plant operator obtains the confirmatory count.

3. Reject milk shipments from the dairy farm if the confirmatory somatic cell count under par. (2) still exceeds 1,000,000 per ml. The milk producer may not ship cow or sheep milk from the dairy farm to any dairy plant until a dairy plant operator conducts another somatic cell count and finds that the count no longer exceeds this number.

Note: The department will suspend a grade A farm permit if 3 of the last 5 reported somatic cell counts exceed the standard under s. ATCP 65.70(4), regardless of whether any somatic cell count exceeds the immediate response level under this subsection. See s. ATCP 65.920.

Note: Under s. ATCP 65.920, the department may suspend a milk producer license if somatic cell counts continue to exceed the standard under s. ATCP 65.70 (4), regardless of whether any somatic cell count exceeds the immediate response level under this subsection. If 2 of the last 4 reported somatic cell counts exceed the standard under s. ATCP 65.70 (4), the department will at least send a warning notice to the producer. See s. ATCP 65.920.

(h) *Laboratory reporting.* A laboratory that performs somatic cell counts under this subsection for a dairy plant operator may report the somatic cell counts for the dairy plant operator.

(5) TEMPERATURE. The temperature of milk received or collected from a dairy farm more than 2 hours after the most recent milking shall not exceed 45° F. (7° C.), or 50° F. (10° C.) in the case of grade B milk in cans. The temperature of blended milk, consisting of milk from 2 or more milkings, that was received or collected less than 2 hours after the most recent milking shall not exceed 45° F. (7° C.)

(6) PESTICIDES AND TOXIC SUBSTANCES. The milk shall be free of pesticides and toxic substances.

ATCP 65.72 Drug residue testing. (1) MONTHLY TESTING OF PRODUCER MILK SHIPMENTS. During every month in which a dairy plant or milk contractor licensed as a dairy plant receives milk from a milk producer, the dairy plant operator shall perform a drug residue test on a milk sample obtained from that producer under s. ATCP 82.12 The drug residue test shall be sensitive, at a minimum, to beta lactam drug residues.

(2) NEW MILK PRODUCER; INITIAL TESTING. A dairy plant operator or milk contractor licensed as a dairy plant shall perform a drug residue test on a milk sample collected from the first milk shipment received from a milk producer. The drug residue test shall be sensitive, at a minimum, to beta lactam drug residues and any other drug residues for which testing is required under sub. (3) (b). If the sample tests positive for any drug residue, the dairy plant operator shall report the result to the division and the producer within the time prescribed in sub. (9).

(3) TESTING BULK LOADS. (a) *Beta lactam drug residues; routine bulk load testing.* Every dairy plant operator shall perform a drug residue test on every bulk load of raw milk offered for

sale upon delivery at that dairy plant. The drug residue test shall be approved by the division and detect, at a minimum, beta lactam drug residues.

(b) *Other drug residues; random bulk load testing.* 1. In addition to performing routine beta lactam tests under par. (a), the operator of a dairy plant shall randomly test bulk milk deliveries received at that dairy plant for other drug residues whenever random testing is required by the division under subd. 2. The random testing program shall be designed so that, during any consecutive 6-month period, a milk shipment from each producer is included in at least 4 separate bulk load tests in each of 4 separate months.

2. The division may issue a periodic written notice to dairy plant operators, requiring dairy plant operators to perform random tests under subd. 1. for drug residues specified in the division's notice. The division shall issue the same notice to every dairy plant licensed by the department. The notice shall specify the effective date of the random testing requirements and the period of time during which the random testing requirements remain in effect.

3. A dairy plant operator may test a bulk milk delivery to detect residues of one or more drugs for which the division has not required testing under subd. 2. The dairy plant shall follow the procedures in pars. (c), (d) and (e).

(c) *Bulk load testing procedure.* Whenever a dairy plant operator performs a drug residue test on a bulk load of milk under par. (a) or (b), the operator shall perform the test on a sample taken from the bulk milk tanker. Sufficient agitation or a milk sampling method approved by the division shall be used to ensure that the sample is representative of the contents of the tanker. The test shall be completed before the bulk load is commingled with any other producer's milk and before any of the milk in the bulk load is processed. For testing purposes under pars. (a) and (b), a milk shipment received in cans is considered a bulk load.

(d) *Responsibility for follow-up testing.* If a bulk load of milk yields a confirmed positive test result for drug residue, and if the dairy plant receiving that milk from producers is not the dairy plant to which those producers are assigned for licensing purposes, under s. ATCP 65.02, the operator of the receiving dairy plant shall immediately notify the operator of the assigned dairy plant. The assigned dairy plant is responsible for performing follow-up tests on producer samples under sub. (4), and for rejecting producer shipments under sub. (5).

(e) Testing with an unapproved method. If the dairy plant uses a testing method that is not approved by the division and detects residues of one or more drugs for which the division has not required testing, under subd. 2., that result shall be treated as a valid test result and reported to the division. The test result shall then either be confirmed under sub. (4) using a drug residue detection method approved by the division or the milk must be discarded under sub. (5). The dairy plant may recover the milk value, under sub. (6), if the confirmatory test result is obtained using a drug residue detection method approved by the division.

(f) Testing of frozen sheep milk for drug residues. A sheep milk producer intending to freeze the sheep milk before shipment must either sample or test the sheep milk for drug residues before bagging and freezing the sheep milk. The sample or test result must remain with the bag or bags of frozen sheep milk to which the sample or test result pertains. Each bag of frozen sheep milk shall be labeled to indicate the grade of milk, the dairy plant receiving the milk, the sheep milk producer, the total number of bags to which the sample or test result pertains, and the date on which the bag was filled with sheep milk. Sheep milk samples must be frozen within 24 hours of sampling, must be maintained at -15°C (5°F) or colder (documentation of storage temperature maintained) and must be tested with 60 days of sampling.

(4) DRUG RESIDUE FOUND IN BULK LOAD; FOLLOW-UP TESTING. If a bulk load of milk yields a confirmed positive test result for drug residue under sub. (3), the dairy plant operator shall perform a drug residue test on each of the individual milk producer samples collected for that bulk load under s. ATCP 82.12. The dairy plant operator shall test each milk producer's sample before collecting any further milk from that producer. The drug residue test performed on each producer sample shall be sensitive to the same drug residue that was detected in the bulk load. If a milk producer's sample tests positive for any drug residue, the dairy plant operator shall perform a confirmatory test using the same test method and sample. The dairy plant operator shall perform the confirmatory test in duplicate, with single positive and negative controls. If either confirmatory test result is positive for a drug residue, the milk producer's sample is considered positive for that drug residue.

(5) DRUG RESIDUE FOUND IN BULK LOAD; LOAD REJECTED. If a bulk load of milk from one or more milk producers yields a confirmed positive test result for drug residue under sub. (3), the dairy plant operator shall reject the entire bulk load. Milk from a rejected bulk load may not be used for human food. The dairy plant operator shall denature or take responsibility for disposing of the rejected bulk load in a manner that precludes its use for human food.

(6) REJECTED BULK LOAD; DAIRY PLANT RECOVERY FROM PRODUCERS OR MILK CONTRACTORS. (a) *Dairy plant loss recovery.* If a dairy plant operator properly rejects a bulk load of milk under sub. (5), the dairy plant operator may recover the value of that bulk load from producers whose milk samples, representing milk shipments contained in that bulk load, yield a confirmed positive test result for drug residue under sub. (4). If the milk has been procured by the dairy plant from a milk contractor, the dairy plant operator may recover the value of that bulk load from the milk contractor, who may then recover the value of that bulk load from the milk

producers. The dairy plant operator may recover what would have been the value of the bulk load, had the load not yielded a confirmed positive test result for drug residue. The dairy plant operator shall also recover any additional bulk load disposal, transportation, and testing costs that the dairy plant operator incurs because the bulk load yielded a confirmed positive test result for drug residue.

(b) *Pro rata recovery.* The dairy plant operator, or milk contractor, if recovering milk costs under par. (a), shall recover, from each producer identified in par. (a), a pro rata share of the total recovery amount under par. (a). The pro rata recovery from each producer shall be based on the size of that producer's shipment compared to those of any other producers in the same bulk load. If there is only one producer identified in par. (a), the operator shall recover the entire amount from that producer.

(c) *Recovery deadline.* The dairy plant operator or milk contractor shall recover the full amount owed by each offending milk producer, under par. (b), within 90 days after that producer's milk sample yields a confirmed positive test result for drug residue under sub. (3). If the dairy plant operator or milk contractor fails to recover the full amount within that time period, the dairy plant operator shall give the department a written explanation.

(d) *Payroll deduction.* A dairy plant operator or milk contractor may deduct the amount owed by an offending milk producer, under par. (b), from the dairy plant operator's payroll obligation to that offending milk producer.

(e) *Notice of deduction.* A dairy plant operator or milk contractor shall give a milk producer at least 30 days prior written notice of any deduction, under par. (d), unless the milk producer transfers to another dairy plant operator. The notice shall state all the following:

1. The basis for the deduction.

2. The total amount of the deduction.

3. The date on which the dairy plant operator or milk contractor will make each deduction.

4. That the dairy plant operator or milk contractor will meet with the milk producer to discuss the deduction, at the milk producer's request.

(f) *Meeting to discuss recovery.* A dairy plant operator or milk contractor shall meet with a milk producer, at the milk producer's request, to discuss the recovery from that milk producer under this subsection. The dairy plant operator or milk contractor shall meet with the milk producer within 10 days after the milk producer requests the meeting, unless the milk producer requests a later meeting date. If the milk producer contests the validity of the recovery, and the matter is not resolved, the dairy plant operator or milk contractor shall notify the milk producer that the milk producer may request a hearing before the department under par. (g).

(g) *Hearing request.* If a milk producer contests the validity of a recovery under this subsection, and if the parties do not resolve the matter after meeting under par. (f), the producer may request a hearing before the division. A request for hearing does not automatically stay a recovery under this subsection.

(h) *Informal hearing.* If a milk producer requests a hearing under par. (g), the division shall hold an informal hearing by telephone or at the division's nearest office. The division shall hold the informal hearing within 20 days after the division receives the hearing request, unless the milk producer agrees to a later hearing date. The division shall include the producer and the dairy plant operator or milk contractor in the informal hearing.

(i) *Formal hearing.* If an informal hearing, under par. (h), does not resolve the matter, a milk producer may request a contested case hearing before the department under ch. ATCP 1 and ch. 227, Stats. A request for hearing does not automatically stay a recovery under this subsection. If

the department grants a milk producer's request for hearing, the department shall include the milk producer and the dairy plant operator or milk contractor as parties to the hearing.

(j) *Invalid recovery.* If the department finds that a recovery under this subsection is invalid, the department may prohibit the recovery or order the dairy plant operator or milk contractor to repay the producer. The division may issue an order under this paragraph after the division holds an informal hearing under par. (h). If the division issues an order under this paragraph, the dairy plant operator may request a contested case hearing under ch. ATCP 1 and ch. 227, Stats., to contest the division's order. A request for hearing does not automatically stay the division's order.

(7) PRODUCER MILK SHIPMENTS REJECTED. (a) *Dairy plant to reject.* A dairy plant operator shall immediately notify a milk producer directly, or via the milk contractor from whom the producer's milk was procured, and shall reject that producer's milk shipments as required under par. (b), if any of the following occurs:

1. A sample of the producer's milk, under sub. (1), yields a confirmed positive test result for drug residue.

2. A sample of the producer's milk, under sub. (4), yields a confirmed positive test result for drug residue.

3. A sample of the producer's milk yields a confirmed positive test result for drug residue after that milk has been commingled with milk from other producers, regardless of whether the drug residue test is required under this chapter.

(b) *Producer milk rejected.* If a dairy plant operator is required to reject producer milk shipments under par. (a), the dairy plant operator shall reject all milk produced on that dairy farm

until a sample of that milk tests negative for drug residues by the same or an equivalent test at a laboratory that is certified under s. ATCP 77.03 (2) (c) to perform confirmatory tests.

(c) *Rejected milk; use prohibited.* If a dairy plant operator rejects a producer's milk under par. (b), no person may do any of the following:

1. Ship, collect, or use that milk for human food.

2. Commingle that milk with milk from any other producer.

(d) *Transfer between dairy plants.* If a dairy plant operator rejects a producer's milk under par. (b), the milk producer or a milk contractor may not ship that producer's milk to another dairy plant until a dairy plant operator tests that producer's milk and the milk tests negative for drug residue on the same or an equivalent test at a laboratory that is certified under s. ATCP 77.03 (2) (c) to perform confirmatory tests.

(8) REPORTING DRUG RESIDUE FINDINGS; BULK LOADS. Within 2 hours after a bulk load of milk yields a confirmed positive test result for drug residue under sub. (2), the dairy plant operator shall report the drug test result to the division by telephone, electronic mail, or facsimile (FAX) transmission. The dairy plant operator shall confirm the report in writing, in a form approved by the division, within 3 business days after the drug residue test is completed. The report shall indicate the result of the drug residue test, the volume of milk contained in the bulk load, and the dairy plant's disposition of that milk.

(9) REPORTING DRUG RESIDUE FINDINGS; PRODUCER MILK SHIPMENTS. (a) *Dairy plant to report.* Whenever any of the following occurs, the dairy plant operator that performs the drug residue test shall report the test result to the division under par. (b):

1. A milk producer sample, under sub. (1), yields a confirmed positive test result for drug residue.

2. A milk producer sample, under sub. (4), yields a confirmed positive test result for drug residue.

3. A sample of a producer's milk yields a confirmed positive test result for drug residue after that milk has been commingled with milk from other producers, regardless of whether the drug residue test is required under this chapter.

(b) *Form of report.* Whenever a dairy plant operator is required to report a drug residue test result under par. (a), the dairy plant operator shall report that result to the division by telephone, electronic mail, or facsimile (FAX) transmission. The dairy plant operator shall make the report within 2 hours after the drug residue test is completed. The dairy plant operator shall confirm the report in writing, on a form approved by the division, within 3 business days after the drug residue test is completed.

(10) INSPECTION BY DIVISION; REINSPECTION FEE. The division may, in its discretion, inspect a dairy farm in response to any positive drug residue test report under sub. (8) or (9). The division shall charge a reinspection fee for the inspection under s. ATCP 65.02 (19). The division shall not charge a reinspection fee if it makes its inspection more than 3 weeks after the dairy plant operator reports the drug residue test result to the division.

(11) DRUG RESIDUE TEST RESULTS. (a) *Positive test result; general.* For purposes of this section and s. ATCP 65.922, a drug residue test is considered positive if the detected amount of drug residue exceeds the action level specified for that drug under par. (b). The action levels, under par. (b), do not establish legal tolerances for drug residues in milk, nor do they preclude the department from taking enforcement action where drug residues are present at levels below these action levels.

(b) *Specified drug tests; positive test result.* In a test for any of the following drugs, the action level is exceeded whenever the drug residue level found in the test exceeds the level specified below:

1. Ampicillin 10 ppb
2. Amoxicillin 10 ppb
3. Cephapirin 20 ppb
4. Ceftiofur 100 ppb
5. Cloxacillin 10 ppb
6. Novobiocin 100 ppb
7. Penicillin G 5 ppb
8. Sulfadimethoxine 10 ppb
9. Tetracyclines* 300 ppb

Note: Action levels specified under this paragraph are based on tolerances and/or target testing levels specified by the United States food and drug administration, and identified in a memorandum from FDA's Milk Safety Branch, M-I-05-5, September 27, 2005. A copy of the memorandum is on file with the department, and is available upon request.

For drugs identified with an asterisk (*), the levels in this paragraph are based on "safe levels" specified by FDA. "Safe levels" are merely enforcement guides and do not constitute legal tolerances. "Safe levels" are not binding on the courts or the department. They do not limit the department's discretion in any way, and they do not protect milk producers or milk itself from enforcement action. "Safe levels" do not constitute animal drug tolerances under section 512 (b) of the federal food, drug and cosmetic act.

(c) *Test result presumed valid.* For purposes of this section and s. ATCP 65.922, whenever a dairy plant operator reports a confirmed positive test result to the division under sub. (9), that test result is presumed to be valid. The milk producer may appeal the test result in an informal hearing under s. ATCP 65.928.

(12) LABORATORY REPORTING. A laboratory that performs tests under this section for a dairy plant operator may report the test results for the dairy plant operator.

(13) TIMELY TESTING. Drug residue tests required under this section shall be completed within 72 hours after the tested milk, or any portion of the tested milk, was first collected from a dairy farm.

Note: If a drug residue test is performed on a bulk load of milk collected from several dairy farms, the test must be completed within 72 hours after the bulk milk weigher and sampler collects milk from the first farm. Confirmation of positive drug residue screening tests, at a different laboratory than the laboratory which performed the screening tests, as required under s. ATCP 65.78 (1)(b) 3., must be completed within the same 72-hour period.

ATCP 65.74 Milk and dairy products; quality standards. (1) MILK HELD AT DAIRY PLANT; BACTERIAL COUNT. The bacterial count of commingled grade A milk held at a dairy plant before pasteurization may not exceed 300,000 per ml. The bacterial count of grade B milk held at a dairy plant before pasteurization or processing may not exceed 750,000 per ml.

(2) PASTEURIZED GRADE A DAIRY PRODUCTS. (a) Bacterial counts in pasteurized grade A dairy products other than cultured dairy products may not exceed the following levels:

1. 20,000 per ml., except as provided in subd. 2. and 3.

2. 10,000 per g. for nonfat dry milk.

3. 30,000 per ml. for condensed milk, whey, whey products, and dried whey.

(b) Coliform counts in pasteurized grade A dairy products may not exceed 10 per ml. or per gram, except that coliform counts in bulk milk tanker shipments of pasteurized grade A dairy products may not exceed 100 per ml.

(c) In pasteurized grade A milk without added flavors or ingredients, other than vitamins, there shall be fewer than 350 milliunits of phosphatase per liter as determined by the Fluorophos ALP method, the Charm Paslite Alkaline Phosphatase method or another test method approved by the department.

(d) The yeast and mold count of pasteurized cottage cheese may not exceed 10 per gram.

(3) PASTEURIZED GRADE B DAIRY PRODUCTS. (a) Bacterial counts in pasteurized grade B dairy products, other than cultured dairy products or frozen desserts containing nuts or other inclusions, may not exceed the following levels:

1. 20,000 per ml., except as provided in subd. 2. or 3.

2. 30,000 per ml. for condensed milk, whey, whey products, dried whey, and nonfat dry milk.

3. 50,000 per gram for frozen desserts, except that the bacterial count for frozen-dessert mixes may not exceed 20,000 per gram.

(b) Coliform counts in pasteurized grade B dairy products, other than grade B dairy products made with natural or added cultures and all natural cheeses, may not exceed 10 per ml. or per gram, except that coliform counts in bulk milk tanker shipments may not exceed 100 per ml.

(4) FORTIFIED DAIRY PRODUCTS. Whenever milk or a fluid milk product is fortified with vitamin A or D the fortification shall comply with Appendix O of the PMO.

(5) PATHOGEN CONFIRMED IN READY-TO-EAT DAIRY PRODUCT; SALE PROHIBITED. A dairy plant operator may not sell or distribute any ready-to-eat dairy product in which a microbiological test or laboratory analysis has confirmed the presence of a pathogenic organism or toxin. Results of the microbiological test or laboratory test shall be reported to the division, under s. ATCP 65.46 (2).

Note: Copies of PMO Appendix O are on file with the department and the legislative reference bureau. Copies may be obtained from the department at cost or online at www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk.

ATCP 65.76 Milk quality testing. (1) REQUIRED TESTING. (a) A dairy plant operator shall test raw milk from dairy farms as required under this chapter.

(b) A dairy plant operator shall test milk and dairy products held or processed at a dairy plant for compliance with standards specified under s. ATCP 65.74 (1) to (4). The dairy plant operator

shall test the milk and dairy products as often as necessary to provide reasonable statistical assurance of compliance.

(2) LABORATORY. (a) Except as provided under par. (b), milk quality tests required under this chapter shall be performed in a laboratory that is all of the following:

1. Approved by the department to conduct milk quality tests.

2. Certified by the department under ch. ATCP 77.03, or by an equivalent certifying agency in another state, to conduct milk quality tests.

(b) A laboratory that is not certified under s. ATCP 77.03 to perform a drug residue test under s. ATCP 65.72 may perform that test as a screening test if all of the following apply:

1. The department has approved that laboratory to perform that screening test under s. ATCP 77.23 (1).

2. The department has approved the person who performs the screening test under s. ATCP 77.23 (2).

3. A different laboratory performs a confirmatory test if the screening test result is positive for drug residue. The laboratory performing the confirmatory test shall be certified to do so under s. ATCP 77.03. The laboratory shall perform the confirmatory test on the same test sample using the same or an equivalent test method and shall complete the confirmatory test within the time period specified in s. ATCP 65.72 (8).

(c) The department may withdraw its approval under par. (a) or (b) for cause, including false or inaccurate test results or reports, or failure to conduct tests according to required procedures.

(3) ANALYSTS. (a) Except as provided in par. (b) or (c), no individual may perform a milk test under ss. ATCP 65.70 and 65.72 unless the department has certified that individual under s. ATCP 77.22 to perform that test.

(b) Pursuant to s. ATCP 77.23 (2), the department may approve an individual to perform a drug residue test under s. ATCP 65.72 as a screening test, even though the individual is not certified under s. ATCP 77.22 to perform that test as a confirmatory test.

(c) Bulk load tests for drug residues under s. ATCP 65.72 shall be conducted at the receiving dairy plant by any of the following:

1. An individual approved by the department to conduct drug residue tests.

2. An individual who performs drug residue tests only under the direct supervision of an individual approved and certified under subd. 1.

Note: A laboratory performing milk quality tests must be certified under ch. ATCP 77.

(4) TEST METHODS. Milk testing under ss. ATCP 65.70 and 65.72 shall use test methods prescribed in the applicable FDA 2400 series laboratory evaluation forms, published by the United States department of health and human services, public health service, food and drug administration, that are in effect on February 1, 2008. If no FDA form applies, testing shall be conducted according to methods prescribed in the "Standard Methods for the Examination of Dairy Products," 17th Edition (2004), or in "Official Methods of Analysis of AOAC International," 18th Edition (2005).

Note: Copies of the FDA 2400 series laboratory evaluation forms in effect on February 1, 2008, are on file with the department and the legislative reference bureau. To find out how to obtain a copy of these forms, you may contact the department at the following address:

Wisconsin Department of Agriculture, Trade and Consumer Protection
Division of Food Safety
Laboratory Certification Program
P.O. Box 8911, Madison, WI 53708-8911
Telephone: (608) 224-4712

The American Public Health Association's "Standard Methods for the Examination of Dairy Products," 17th Edition (2004), is on file with the department and the legislative reference bureau and may be obtained from the American Public Health Association, Inc., 800 I Street, NW, Washington, D.C. 20001, telephone 202-777-2742, website www.apha.org.

The "Official Methods of Analysis of AOAC International," 18th Edition (2005), is on file with the department and the legislative reference bureau and may be obtained from AOAC International, 2275 Research Blvd., Rockville, MD 20850, telephone 800-379-2622, website www.aoac.org.

(5) BACTERIA COUNTS. Bacteria counts required under s. ATCP 65.70 and bacteria counts that may affect the amount paid to a milk producer shall be obtained by means of a standard plate count, plate loop count, or petrifilm aerobic count method.

(6) DRUG RESIDUES. Drug residue tests required under s. ATCP 65.72 shall be performed according to s. ATCP 65.72.

(7) SOMATIC CELLS. Somatic cell counts required under s. ATCP 65.70 (4) and somatic cell counts that may affect the amount paid to a milk producer shall be obtained by means of a direct microscopic somatic cell count or an electronic somatic cell count. The Pyronin Y-Methyl green stain test may be used in place of a direct microscopic somatic cell count or electronic somatic cell count for goat milk and shall be used to confirm a direct microscopic somatic cell count or electronic somatic cell count on goat milk that exceeds 1,000,000 per ml.

(8) TESTING DEADLINES. A milk quality test shall be conducted within the time period specified by the test method.

ATCP 65.78 Milk quality test samples. (1) GENERAL. (a) Whenever a dairy plant operator performs a milk quality test on a bulk milk shipment from a milk producer, the dairy plant operator shall perform that milk quality test on a test sample collected under s. ATCP 82.12.

(b) Whenever a dairy plant operator performs a milk quality test on shipment of milk in cans from a milk producer, the dairy plant operator shall perform that milk quality test on a test sample collected under sub. (3).

(c) Notwithstanding pars. (a) and (b), a dairy plant operator may use a composite sample, under sub. (4), to perform a Babcock test for milkfat or to perform another milk quality test approved by the division under sub. (4). A composite sample shall be compiled from fresh milk samples collected under par. (a) or (b).

(d) This subsection does not apply to a bulk load test for drug residues under s. ATCP 65.72 (3).

(e) Upon reasonable notice from the division, a dairy plant operator shall provide the division with samples of producer milk collected under s. ATCP 65.38. The division may request samples once every 4 months, or more often as the department considers necessary for animal health and milk quality testing. Every sample shall be marked with the identification number of the individual producer from whom the sample was collected, and shall also indicate the date on which the sample was collected. A sample shall be kept at a temperature of 32° to 40° F. (0° F. to 4 ° C.) until it is transferred to the custody of the department.

(2) TEST SAMPLES REFRIGERATED. At all times prior to testing, a test sample under sub. (1) shall be kept refrigerated at a temperature of 32 to 40° F. (0 to 4° C.). Test samples kept at a dairy plant or testing laboratory shall be kept in a refrigerated storage facility used only for storing test samples and laboratory supplies.

(3) COLLECTING TEST SAMPLES FROM SHIPMENTS OF MILK IN CANS. (a) If a producer ships milk to a dairy plant in cans, rather than in bulk, the dairy plant operator shall collect a test sample from each milk shipment immediately after that milk shipment is transferred to the weigh tank at the dairy plant, and before it is commingled with any other milk shipment. The weigh tank shall be constructed so that milk poured into the weigh tank is completely mixed.

(b) If a weigh tank is not large enough to accommodate a producer's entire milk shipment, so that multiple weighings are needed, the dairy plant operator shall divide the shipment as evenly as possible between weighings and collect a sample from each weighing. The samples shall be of equal volume and shall be combined to form a single sample representing the entire shipment from the producer. The dairy plant operator may not split the contents of any single can of milk between weighings, but shall include all of the contents of that can in the same weighing.

(4) COMPOSITE SAMPLES. (a) A dairy plant operator may use a composite sample to perform a Babcock test for milkfat, but may not perform any other milk quality test on a composite sample except with the division's written authorization. A composite sample shall be compiled according to this subsection.

(b) A composite sample shall include a representative sample of milk from each of 2 or more milk shipments represented by the composite sample. No composite sample may include milk from more than 16 milk shipments. Each component sample included in the composite sample shall have the same volume and shall include at least 10 ml. of milk. A composite sample shall include at least 150 ml. of milk.

(c) A composite sample container shall have a capacity of at least 240 ml. The composite sample container shall include an effective permanent closure that is attached to the container. The composite sample container shall be marked to identify the producer and the milk shipments represented in the composite sample.

(d) A composite sample representing a producer's bulk milk shipments shall be compiled from fresh milk samples collected from those shipments under s. ATCP 82.12. On the same day that a producer's bulk milk shipment is received by the dairy plant operator, or by 12:00 noon of

the following day, the dairy plant operator shall transfer, to the composite sample, at least 10 ml. of milk from the sample collected from that milk shipment under s. ATCP 82.12.

(e) A composite sample representing a producer's shipments of milk in cans shall be compiled from milk samples collected from those shipments according to sub. (3).

(f) A dairy plant operator shall preserve a composite sample by adding potassium dichromate, or another preservative approved by the division, to the composite sample. Not less than 100 mg., nor more than 190 mg. of potassium dichromate may be used in each composite sample to obtain a concentration of 20 mg. per 30 ml. of milk in the completed sample.

Note: Potassium dichromate is available in tablets containing 40 mg. of active ingredient per tablet. The use of these tablets at the rate of one tablet per 2 fl. oz. of milk in a completed composite sample is equivalent to the concentration specified under par. (f). Labeling requirements and limitations on the disposal of milk samples preserved with potassium dichromate are contained in s. ATCP 30.15 (2) (b).

ATCP 65.80 Milk quality test records and reports. (1) TEST RECORDS; GENERAL. (a) A person performing a milk quality test shall immediately record the test result and sign the test record. The test record shall specify the date of the test, including the year, the identification number of the milk producer, and the milk shipment from which the milk sample was collected.

(b) No test record may be altered except that errors, if any, may be corrected by marking a single line through the original entry and inserting the correct entry immediately adjacent to the original. A corrected entry shall be initialed by the person who made the corrected entry.

(c) The division may authorize a dairy plant to keep test records in electronic form if the division finds that all of the following requirements are met:

1. The records are effectively secured against loss or tampering.

2. The records can be readily retrieved for inspection by the dairy plant operator and the division.

3. The person who performs the test identifies himself or herself on the test record, by an electronic method that is equivalent to a personal signature.

4. If an erroneous test record is corrected, the correction is identified so that the reader can easily compare the corrected record to the original record.

(2) RECORDS RETAINED BY DAIRY PLANT OPERATOR. A dairy plant operator shall retain records required under this section for the time period specified under s. ATCP 65.44 and shall make the records available for inspection and copying by the division upon request.

ATCP 65.82 False samples, test results or reports. No person may do any of the following or conspire with another person to do any of the following:

(1) Falsely identify milk samples.

(2) Submit a false milk sample to the department, a dairy plant operator, or a testing laboratory.

(3) Falsify any milk quality test or test result.

(4) Make any false or misleading record or report related to a milk quality test.

(5) Withhold any milk quality test report required under this chapter.

ATCP 65.84 Milk component testing. (1) LICENSING OF PERSON PERFORMING TEST. No person may perform any milk component test unless that person is licensed to perform milk component tests, either as a buttermaker or cheesemaker under s. 97.17, Stats., or as a milk and cream tester under s. 98.145, Stats.

(2) QUALIFICATION OF PERSON USING AUTOMATED TESTING DEVICE. No person may use an automated testing device to perform any milk component test unless that person is trained and qualified to use automated testing devices, and that fact is stated on his or her license under s. 97.17 or 98.145, Stats.

(3) PAYMENT BASED ON MILK COMPONENT TESTS. No dairy plant operator, including a milk contractor that submits a milk producer license application on behalf of a milk producer and thereby certifies that the milk producer's dairy farm and milking operations comply with applicable requirements under this chapter, may adjust the price paid to any milk producer based on the results of any milk component test or somatic cell test unless the dairy plant operator does all of the following:

(a) Bases the price adjustment on either the arithmetic or weighted average of all test results obtained for that producer during the pay period to which the price adjustment applies. The dairy plant operator shall use the same method for computing average test results for all producers shipping milk to the dairy plant.

(b) Tests at least 3 milk shipments from that producer at regular intervals throughout the pay period to which the price adjustment applies or tests composite samples representing all milk shipments from that milk producer during that pay period.

ATCP 65.86 Milk component test methods. (1) GENERAL. Milk component tests shall be performed using any of the following methods, subject to additional requirements under sub. (2) and (3):

(a) A method described in the American Public Health Association., "Standard Methods for the Examination of Dairy Products," 17th edition (2004).

(b) A method described in the "Official Methods of Analysis of AOAC International," 18th edition (2005).

(c) A method approved in writing by the division.

Note: A "milk component test," as defined under s. ATCP 65.01 (35), means a test that determines the amount of milkfat, protein, total solids, solids-not-fat, or other valuable components in milk, and that may affect the price that a dairy plant operator or milk contractor pays a milk producer for milk.

The American Public Health Association's "Standard Methods for the Examination of Dairy Products," 17th edition (2004), is on file with the division and the legislative reference bureau. Copies may be obtained from the American Public Health Association, 800 I Street, NW, Washington, D.C. 20001, telephone 202-777-2742, website www.apha.org.

The "Official Methods of Analysis of AOAC International," 18th Edition (2005), is on file with the division and the legislative reference bureau. Copies may be obtained from AOAC International, 2275 Research Blvd., Rockville, MD 20850, telephone 800-379-2622, website www.aoac.org

(2) MILKFAT TEST METHODS. (a) Milkfat tests shall be performed using the Babcock method, the ether extraction method, or another test method approved by the division. Babcock and ether extraction tests shall be conducted according to the "Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC) International," 17th edition (2000), except as provided under par. (b).

(b) Each milk sample tested by the Babcock method shall be agitated for at least 3 minutes by the use of a mechanical agitator after pipetting the sample and adding sulfuric acid according to the procedure prescribed under par. (a). A reading device, such as a needlepoint divider or other mechanical divider, that accurately determines milkfat level in a test bottle shall be used in reading all Babcock tests. All Babcock test readings shall be made against a light-colored surface with adequate natural or artificial light. The Babcock test shall be read to the nearest 0.05% by weight.

(3) AUTOMATED MILK COMPONENT TESTING DEVICES. (a) *General calibration requirements.* If an automated testing device is used to perform a milk component test for any milk component, that device shall be calibrated and regularly checked to ensure that it accurately tests for that milk component.

(b) *Specific calibration requirements.* If an automated testing device is used to test for milkfat, protein, total solids, or solids-not-fat in milk, and if the test results may affect the price paid to a milk producer, the testing device shall be calibrated according to this paragraph. The

testing device shall be calibrated, for each relevant milk component, by a tester who is licensed under s. 97.17 or 98.145, Stats., to operate that device.

Note: See s. ATCP 65.78 (2).

1. *Calibration frequency.* A milk component testing device under par. (b) shall be calibrated at all of the following times:

a. Upon installation.

b. At regular 3 month intervals after installation.

c. Immediately after every significant repair or alteration to the testing device.

d. Whenever the mean difference on a daily performance check under par. (c) exceeds plus or minus 0.044% for milkfat or protein or plus or minus 0.084% for total solids or solids-not-fat.

2. *Calibration procedure.* To calibrate a milk component testing device under par. (b), a tester shall use the device to test a set of calibration samples under subd. 3. The milk component testing device shall be adjusted, as necessary, to satisfy all of the following requirements:

a. The performance error on each calibration sample shall be as near as practicable to zero. The performance error is the difference between the known percentage content of each milk component in the calibration sample, as determined by the sample provider, and the percentage content measured by the testing device.

b. The mean difference for the entire set of calibration samples shall be as near as practicable to zero and shall not exceed plus or minus 0.044% for milkfat or protein or plus or minus 0.084% for total solids or solids-not-fat. The mean difference is the sum of the performance errors for the individual calibration samples divided by the number of samples in the set.

c. The standard deviation of test results, calculated for the set of calibration samples according to the formula set forth in the "Official Methods of Analysis of AOAC International,"

18th edition (2005), section 969.16, shall not exceed 0.044 % for milkfat or protein, or 0.084 % for total solids or solids-not-fat.

Note: The "Official Methods of Analysis of AOAC International," 18th edition (2005), is on file with the division and the legislative reference bureau, and may be obtained from AOAC International, 2275 Research Blvd., Rockville, MD 20850, website http://www.aoac.org.

3. *Calibration samples.* A set of calibration samples shall be obtained from a sample provider approved by the division. A set of calibration samples shall consist of at least 12 individual samples, each of which complies with all of the following requirements:

a. Each sample shall be not more than 21 days old.

b. Each sample shall be a fresh milk sample preserved with bronopol (2-bromo-2-nitro-1, 3-propanediol) or another approved preservative. Preservative methods, formulations, and concentrations shall be approved by the division.

c. Each sample shall have a known percentage content of each relevant milk component determined by the sample provider under pars. (e) to (h).

(c) *Daily performance check.* 1. If an automated testing device is used to test for milkfat, protein, total solids, or solids-not-fat in milk, and if the test results may affect the price paid to a milk producer, the device shall be subjected to a daily performance check before each day's testing. The daily performance check shall be conducted, for each relevant milk component, by a tester who is licensed under s. 97.17 or 98.145, Stats., to operate the testing device.

2. To conduct a daily performance check under subd. 1., a tester shall test a set of daily performance check samples under subd. 4. Based on the daily performance check, the tester shall do all of the following:

a. Determine the performance error of the testing device with respect to each daily performance check sample. The performance error is the difference between the known

percentage content of each milk component in that sample, as determined by the sample provider, and the percentage content measured by the testing device.

b. Based on the performance errors for the individual samples under subdivision paragraph a, calculate the mean difference for the set of daily performance check samples. The mean difference is the sum of the performance errors for the individual samples, divided by the number of samples in the set.

3. If, on a daily performance check under subd. 1., the mean difference calculated under subd. (2) (b) exceeds plus or minus 0.044% for milkfat or protein or plus or minus 0.084% for total solids or solids-not-fat the testing device shall not be used until it is recalibrated under par. (b).

4. A set of daily performance check samples shall be obtained from a sample provider approved by the division. A set shall consist of at least 5 individual samples, each of which complies with all of the following requirements:

a. Each sample shall be not more than 21 days old.

b. Each sample shall be a fresh milk sample preserved with bronopol (2-bromo-2-nitro-1, 3-propanediol) or another approved preservative. Preservative methods, formulations, and concentrations shall be approved by the department.

c. Each sample shall have a known percentage content of each relevant milk component, determined by the sample provider under pars. (e) to (h).

(d) *Reference checks.* 1. If an automated testing device is used to test for milkfat, protein, total solids, or solids-not-fat in milk, and if the test results may affect the price paid to a milk producer, that device shall be subjected to a daily reference check under subd. 2 and hourly reference checks under subd. 3.

2. A daily reference check required under subd. 1 shall be done in accordance with all of the following requirements:

a. A daily reference check shall be conducted before each day's testing, at the same time that the dairy plant operator conducts the daily performance check under par. (c). The daily reference check shall be conducted, for each relevant milk component by a tester who is licensed under s. 97.17 or 98.145, Stats., to operate the testing device.

b. To perform a daily reference check, a tester shall perform 10 tests on a reference sample. The reference sample may be a homogenized milk sample prepared by the dairy plant operator, or it may be a daily performance check sample obtained from a sample provider approved by the department under par. (c) 4. The 10 test results shall be averaged and the average result shall be used as a comparison value for the hourly reference checks under subd. 3.

3. An hourly reference check required under subd. 1 shall be done in accordance with all of the following requirements:

a. An hourly reference check shall be conducted for each milk component before each hour's testing for that component. To conduct an hourly reference check, a tester shall test the same reference sample used for the daily reference check under subd. 2.

b. For each relevant milk component the hourly reference check result shall be compared to the average result obtained on the daily reference check under subd. 2. If an hourly reference check result differs from the average result on the daily reference check by more than 0.034% for milkfat or protein or 0.064% for total solids or solids-not-fat, the testing device shall not be used until the condition causing the difference is found and corrected. Test results obtained before the device is corrected, and after the last previous conforming reference check, shall not be used in determining the amount paid to milk producers.